Attorney's Docket No. 033303-012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	
Prem S. Paul et al.	Group Art Unit: 1648
Application No.: 09/810,501	Examiner: D. Wortman
Filed: March 19, 2001	Appeal No.:
For: POLYNUCLEIC ACIDS ISOLATED FROM A PORCINE REPORDUCTIVE AND RESPIRATORY SYNDROM VIRUS (PRRSV), PROTEINS ENCODED BY THE POLYNUCLEIC ACIDS, VACCINES BASED ON THE PROTEINS AND/OR POLYNUCLEIC ACIDS, A ...	

BRIEF FOR APPELLANT

Mail Stop APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This appeal is from the decision of the Primary Examiner dated March 4, 2004 (Paper No. , finally rejecting claims 30, 31 and 39-41, which are reproduced as an Appendix to this brief.

☒ A check covering the ☐ $165.00 (2402) ☒ $330.00 (1402) Government fee and two extra copies of this brief are being filed herewith.

☐ Charge ☐ $165.00 (2402) ☐ $330.00 (1402) to Credit Card. Form PTO-2038 is attached.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in triplicate.

IX. Conclusion

In light of the foregoing, Claims 30, 31 and 39-41 are patentable, and a finding of such is respectfully requested.

Respectfully submitted,

Burns, Doane, Swecker & Mathis, L.L.P.

Date September 7, 2004 By: Sharon E. Crane

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APPELLANTS' BRIEF ON APPEAL

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TABLE OF AUTHORITIES

Statutes

I. Real Party in Interest

The present application is assigned to Iowa State University Research Foundation, Inc. and American Cyanamid Company.

II. Related Appeals and Interferences

The Appellant's / Appellants' legal representative, or assignee, does not know of any other appeal or interferences which will affect or be directly affected by or have bearing on the Board's decision in the pending appeal.

III. Status of Claims

1. (Withdrawn) A purified preparation containing a polynucleic acid encoding at least one polypeptide selected from the group consisting of:

proteins encoded by one or more open reading frames (ORF's) of an Iowa strain of porcine reproductive and respiratory syndrome virus (PRRSV);

proteins at least 80% but less than 100% homologous with those encoded by one or more of ORF 2, ORF 3, ORF 4 and ORF 5 of an Iowa strain of PRRSV;

proteins at least 97% but less than 100% homologous with proteins encoded by one or both of ORF 6 and ORF 7 of an Iowa strain of PRRSV; and

antigenic regions of said proteins which are at least 5 amino acids in length and which effectively stimulate immunological protection in a porcine host against a subsequent challenge with a PRRSV isolate;

and combinations thereof.

2. (Withdrawn) The purified preparation of Claim 1, wherein said polynucleic acid has a sequence selected from the group consisting of the formulas (I), (II) and (III):

5'-α-β-γ-3'	(I)
5'-γ-δ-ε-3'	(II)
5'-α-β-γ-δ-ε-3'	(III)

wherein:

α encodes at least one polypeptide, or antigenic fragment thereof having a length of at least 5 amino acid residues, encoded by a polynucleotide selected from the group consisting of ORF 1a and 1b, ORF 2 and ORF 3 of a PRRSV and regions thereof encoding the antigenic fragments;

β is either a covalent bond or a linking polynucleic acid which excludes a sufficiently long portion of ORF 4 from an hv PRRSV to render the hv PRRSV either low-virulent or non-virulent;

γ is at least one copy of an ORF 5 from an Iowa strain of PRRSV;

δ is either a covalent bond or a linking polynucleic acid which does not materially affect transcription and/or translation of said polynucleic acid; and

ε encodes at least one polypeptide encoded by either a polynucleotide selected from the group consisting of ORF 6 and ORF 7 of an Iowa strain of PRRSV, or a region of ORF 5, ORF 6 and ORF 7 of an Iowa strain of PRRSV encoding an antigenic polypeptide fragment having a length of at least 5 amino acid residues;

and when δ is a covalent bond, γ may have a 3'-end which excludes the region overlapping with the 5'-end of a corresponding ORF 6.

3. (Withdrawn) The purified preparation of Claim 1, wherein said ORF 5 is from a high replication (hr) phenotype.

4. (Withdrawn) The purified preparation of Claim 1, wherein is a polynucleotide encoding an antigenic region of ORF 6.

5. (Withdrawn) The purified preparation of Claim 1, wherein said polypeptide is selected from the group consisting of proteins at least 97% homologous with those encoded by ORF's 6-7 of VR 2385, VR 2429 (ISU-22), ISU-79 and VR 2431 (ISU-3927); proteins at least 90% homologous with proteins encoded by ORF's 2-5 of VR 2385, VR 2429, VR 2430 (ISU-55), VR 2431, ISU-79 and ISU-1894; and antigenic regions of said proteins having a binding affinity of at least 1% of the binding affinity of the full-length protein encoded by the

corresponding ORF 2, 3, 4 or 5 of VR 2385, VR 2429, ISU-79 or VR 2431 or ORF 6 or 7 of VR 2385, VR 2429, VR 2430, VR 2431, ISU-79 or ISU-1894 to a monoclonal antibody which specifically binds to said full-length protein; and combinations thereof.

6. (Withdrawn) The purified preparation of Claim 5, wherein isolated polynucleic acid is selected from the group consisting of ORF 2, ORF 3, ORF 4, ORF 5, ORF 6 and ORF 7 of any one of VR 2385, VR 2429, VR 2431, ISU-79, ISU-3927, ISU-22 and ISU-1894, and combinations thereof.

7. (Withdrawn) The purified preparation of Claim 5, wherein said polypeptide is encoded by at least one of ORF's 2, 3, 5, and 6 of VR 2385, VR 2429, VR 2431, ISU-79, ISU-22 and ISU-1894.

8. (Withdrawn) The purified preparation of Claim 1, wherein said polynucleic acid encodes said homologous protein, and non-homologous residues in said homologous protein are conservatively substituted.

9. (Withdrawn) The purified preparation of Claim 1, wherein said isolated polynucleic acid encodes said antigenic region of at least one of said proteins, said antigenic region having a length of from 5 amino acids to less than the full length of said protein.

10. (Withdrawn) The purified preparation of Claim 9, wherein said antigenic region has a binding affinity to a monoclonal antibody which specifically binds to said protein of at least 1% of the binding affinity of said protein to said monoclonal antibody.

11. (Withdrawn) A purified polypeptide encoded by the polynucleic acid of Claim 1 or 2.

12. (Withdrawn) A purified polypeptide encoded by the polynucleic acid of Claim 5 or 6.

13. (Withdrawn) A vaccine, comprising an effective amount of the polypeptide of Claim 11 to raise an immunological response in a pig against a porcine reproductive and respiratory syndrome virus, and a physiologically acceptable carrier.

14. (Withdrawn) A vaccine, comprising an effective amount of the polynucleic acid of Claim 1 or 2 to raise an immunological response in a pig against a porcine reproductive and respiratory syndrome virus, and a physiologically acceptable carrier.

15. (Withdrawn) The vaccine of Claim 13, wherein said virus causes a disease characterized by one or more of the following symptoms and clinical signs: respiratory distress, fever, and a reproductive condition in a sow selected from the group consisting of abortion, stillbirth, weak-born piglets, type II pneumocyte formation, myocarditis, encephalitis, alveolar exudate formation and syncytia formation.

16. (Withdrawn) The vaccine of Claim 14, wherein said virus causes a disease characterized by one or more of the following symptoms and clinical signs: respiratory distress, fever, and a reproductive condition in a sow selected from the group consisting of abortion, stillbirth, weak-born piglets, type II pneumocyte formation, myocarditis, encephalitis, alveolar exudate formation and syncytia formation.

17. (Withdrawn) A method of protecting a pig from infection by a porcine reproductive and respiratory syndrome virus, comprising administering an effective amount of the vaccine of Claim 13 to a pig in need thereof.

18. (Withdrawn) The method of Claim 17, wherein said vaccine is administered orally or parenterally.

19. (Withdrawn) The method of Claim 18, wherein said vaccine is administered intramuscularly, intradermally, intravenously, intraperitoneally, subcutaneously or intranasally.

20. (Withdrawn) The method of Claim 17, wherein said vaccine is administered to a sow in need thereof.

21. (Withdrawn) An antibody which specifically binds to the polypeptide of Claim 11.

22. (Withdrawn) The antibody of Claim 21, wherein said antibody is a monoclonal antibody.

23. (Withdrawn) An antibody which specifically binds to the polypeptide of Claim 12.

24. (Withdrawn) A method of treating a pig suffering from porcine reproductive and respiratory syndrome, comprising administering an effective amount of the antibody of Claim 21 to a pig in need thereof.

25. (Withdrawn) A diagnostic kit for assaying a porcine reproductive and respiratory syndrome virus, comprising the antibody of Claim 21 and a diagnostic agent which indicates a positive immunological reaction with said antibody.

26. (Withdrawn) The diagnostic kit of Claim 25, wherein said antibody is a biotinylated monoclonal antibody, said diagnostic agent comprises peroxidase-conjugated streptavidin and a peroxidase.

27. (Withdrawn) The diagnostic kit of Claim 26, further comprising aqueous hydrogen peroxide, a protease which digests the porcine tissue sample, a fluorescent dye and a tissue stain.

28. (Withdrawn) A method of diagnosing infection of a pig by or exposure of a pig herd to a porcine reproductive and respiratory syndrome virus, comprising the steps of:

incubating ascites fluid comprising the monoclonal antibody of Claim 22 with a tissue sample for a sufficient length of time and at an appropriate temperature to provide essentially complete immunological binding to occur between said monoclonal antibody and one or more viral antigens in said tissue sample;

incubating a biotinylated linking antibody with the monoclonal antibody-treated tissue sample;

incubating a peroxidase-conjugated streptavidin with the biotinylated antibody-treated tissue; and

detecting said viral antigens.

29. (Withdrawn) The method of Claim 28, further comprising, prior to said incubating steps, the sequential steps of removing endogenous peroxidase from an isolated porcine tissue sample with aqueous hydrogen peroxide, and digesting said tissue sample with a sufficient amount of an appropriate protease to expose said viral antigens; and after said second incubating step, the sequential steps of incubating the peroxidase-conjugated streptavidin-treated tissue with a chromagen and a stain, and detecting said viral antigens, wherein observation of stained chromagen-treated tissue is indicative of the presence of said viral antigens.

30. (Previously presented) A diagnostic kit for the differential diagnosis of North American and European porcine reproductive and respiratory syndrome virus (PRRSV), comprising:

(a) a first primer comprising a polynucleotide having a sequence of from 10 to 50 nucleotides in length which selectively hybridizes to a genomic polynucleic acid

from a North American strain of PRRSV, wherein said North American strain is an Iowa strain of PRRSV selected from the group consisting of ISU-22 (VR 2385 or VR 2386), ISU-22 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), ISU-79 (VR 2474) and ISU-1894 (VR 2475), at a temperature of from 25 to 75°C,

(b) a second primer comprising a polynucleotide having a sequence of from 10 to 50 nucleotides in length which selectively hybridizes to said genomic polynucleic acid from said Iowa strain of PRRSV at a temperature of from 25 to 75°C and being downstream from the sequence to which said first primer hybridizes, and

(c) a reagent which enables detection of an amplified polynucleic acid, wherein said primers selectively amplify said North American strain and not a European PRRSV strain, wherein said European strain is Lelystad.

31. (Original) The diagnostic kit of Claim 30, wherein said reagent is an intercalating dye, the fluorescent properties of which change upon intercalation into double-stranded DNA.

32. (Withdrawn) A method of producing a vaccine which confers immunological protection against a subsequent challenge with a porcine reproductive and respiratory syndrome virus, comprising the steps of infecting a suitable host cell with the polynucleic acid of Claim 1 and culturing said host cell.

33. (Withdrawn) The method of Claim 32, further comprising the step of isolating at least one of said cultured host cell and polypeptide encoded by said polynucleic acid.

34. (Withdrawn) A method of producing the vaccine of Claim 14, comprising the steps of infecting a suitable host cell with at least one of said polynucleic acid and a virus containing said polynucleic acid, culturing said host cell, and isolating said polynucleic acid from said cultured host cell.

35. (Withdrawn) The method of Claim 34, wherein said infecting step employs said virus, and said isolating step comprises:

(A) collecting a sufficiently large sample of said virus to isolate said polynucleic acid,

(B) isolating said polynucleic acid from said collected virus, and

(C) combining said polynucleic acid with said physiologically acceptable carrier.

36. (Withdrawn) The method of Claim 35, wherein said virus or infectious agent is collected from a source selected from the group consisting of a culture medium, cells infected with said virus, and both a culture medium and cells infected with said virus.

37. (Withdrawn) A biologically pure culture of a virus containing the polynucleic acid of Claim 1.

38. (Withdrawn) The biologically pure culture of Claim 37, wherein said polynucleic acid further contains a gene encoding a polypeptide adjuvant or an antigen other than a porcine reproductive and respiratory syndrome virus antigen.

39. (Previously presented) A diagnostic kit for assaying a porcine reproductive and respiratory syndrome virus, comprising:

(a) a first primer comprising a polynucleotide having a sequence of from 10 to 50 nucleotides in length which hybridizes to a genomic polynucleic acid from an Iowa strain of porcine reproductive and respiratory syndrome virus selected from the group consisting of ISU-22 (VR 2385 or VR 2386), ISU-22 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), ISU-79 (VR 2474) and ISU-1894 (VR 2475), and also hybridizes to polynucleic acid from Lelystad virus at a temperature of from 25 to 75°C,

(b) a second primer comprising a polynucleotide having a sequence of from 10 to 50 nucleotides in length which hybridizes to said genomic polynucleic acid from

said Iowa strain of porcine reproductive and respiratory syndrome virus, and also hybridizes to polynucleic acid from Lelystad virus at a temperature of from 25 to 75°C and being downstream from the sequence to which said first primer hybridizes, and

(c) a reagent which enables detection of an amplified polynucleic acid.

40. (Previously presented) The diagnostic kit of Claim 39, wherein said reagent is an intercalating dye, the fluorescent properties of which change upon intercalation into double-stranded DNA.

41. (Previously Added) The diagnostic kit of Claim 39, wherein said primers are selected from the group consisting of SEQ ID NOS:8 and 9, SEQ ID NOS:9 and 10, and SEQ ID NOS:11 and 12.

IV. Status of Amendments

Claims 1-29 and 32-38 have been withdrawn. Claim 30 was amended and Claims 39 and 40 were added in an Amendment dated April 18, 2003. Claim 30 was amended and Claim 41 was added in an Amendment dated December 8, 2003. Claims 30, 31, and 39-41 stand rejected.

V. Summary of the Invention

The invention relates to a diagnostic kit for assaying a porcine reproductive and respiratory syndrome virus (PRRSV), comprising primers suitable for performing polymerase chain reaction (PCR) on a sample to identify certain PRRSV strains.

In a first embodiment, the diagnostic kit comprises upstream and downstream primers comprising 10 to 50 nucleotides, wherein the primers hybridize to both polynucleic acid from (1) Iowa strain PRRSV selected from the group consisting of ISU-22 (VR 2385 or VR 2386), ISU-22 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), ISU-79 (VR 2474) and ISU-1894 (VR 2475), and to (2) Lelystad virus at a temperature of from 25 to 75°C. (Claim 30)

In a second embodiment, the diagnostic kit includes primers which only hybridize to the stated Iowa strains, and not to the Lelystad virus. (Claim 39) The invention also includes a kit comprising the foregoing primers as well as an intercalating dye, wherein the fluorescent properties of the dye change upon intercalation into double-stranded DNA. (Claims 31 and 40) In a most preferred embodiment, the set of primers can be SEQ ID NOS: 8 and 9, SEQ ID NOS: 9 and 10, and SEQ ID NOS: 11 and 12. (Claim 41)

VI. The Issues

Claims 30, 31, 39 and 40 stand rejected under 35 U.S.C. §112, first paragraph, as purportedly failing to comply with the written description requirement. Specifically, the Examiner alleges that Claims 30 and 31 encompass a genus of primers that amplify a North American strain of PRRSV but not European Lelystad virus, but no specific examples are provided in the specification. Applicants maintain that given the extensive description of the sequences of the specific Iowa strains, and the knowledge in the art of the sequence of the Lelystad virus, that one of ordinary skill in the art could, without undue experimentation, design primers with the required characteristics.

With respect to Claims 39 and 40, the Examiner alleges that the claims encompass a genus of primers which hybridize both to Iowa strain viruses and Lelystad virus, but that the "specification describes only five primers, used as three sets of two primers each, that have the required characteristics..." (Office Action dated March 4, 2004 at p. 3.) Applicants maintain that the disclosure of the "three sets of two primers each, that have the required characteristics" as admitted by the Examiner, constitute an adequate number of exemplary sequences so as to entitle Applicants to claim the genus represented by those primer pairs.

Claim 41 stands rejected under 35 U.S.C. §112, second paragraph, because the Examiner alleges that Applicants discussed in the Remarks section of a previous Amendment additional pairs of primers, SEQ ID NOS:1 and 2 and 3 and 4, but only includes primer pairs SEQ ID NOS: 8 and 9, SEQ ID NOS: 9 and 10, and SEQ ID

NOS: 11 and 12 in Claim 41. Applicants maintain that the reference in their Remarks to additional primers being recited in Claim 41 was a typographical error.

VII. Grouping of Claims

Claims 30 and 31 stand or fall together. Likewise, Claims 39 and 40 stand or fall together. Claim 41 stands alone.

VIII. Argument

The present invention relates to a diagnostic kit containing primers for amplifying DNA from porcine reproductive and respiratory syndrome virus (PRRSV). There exist a number of different PRRSV strains, including North American strains, such as the Iowa strains ("ISU") recited in the present claims, and European strains, such as the Lelystad virus. The present specification notes at p. 10, ll. 1-7:

> U.S. PRRSV isolates differ genetically at least in part from European isolates (Conzelman et al., *supra*; Meulenberg et al., *supra*; Murtaugh et al., Proc. Allen D. Leman Conferenc, pp. 43-45, 1993). The genetic differences between U.S. and European isolates are striking, especially since they are considered to be the same virus (Murtaugh, *supra*).

At page 41 of the specification, the specification specifically describes how one would design primers for the differential diagnosis of North American (e.g., Iowa strain) and European (e.g., Lelystad) viruses (Claim 30):

> For example, primers for making relatively large amounts of DNA by the polymerase chain reaction (and if desired, for making RNA by transcription and/or protein by translation in accordance with known in vivo or in vitro methods) can be designed on the basis of sequence information where more than one sequence obtained from a PRRSV genome has been determined (e.g., ORF's 2-5 of VR 2385 and Lelystad virus, or ORF's 6-7 of VR 2385, VR 2429, VR 2430, ISU-79, ISU-1894, VR 2431 and Lelystad virus). A region from about 15 to 50 nucleotides in length having at least 80% and preferably at least 90% identity is selected from the determined sequences. **A region where a deletion occurs in one of the sequences (e.g., of at least 5 nucleotides) can be used as the basis for preparing a selective primer for selective amplification of the polynucleic acid of one**

strain or type of PRRSV over another (e.g., for the differential diagnosis of North American and European PRRSV strains).

[Emphasis added.]

Rejection under 35 U.S.C. §112, first paragraph

Claims 30, 31, 39 and 40 stand rejected under 35 U.S.C. §112, first paragraph, as purportedly failing to comply with the written description requirement. Specifically, the Examiner alleges that Claims 30 and 31 encompass a genus of primers that amplify a North American strain of PRRSV but not European Lelystad virus, but no specific examples are provided in the specification. Applicants maintain that given the extensive description of the sequences of the specific Iowa strains, and the knowledge in the art of the sequence of the Lelystad virus, that one of ordinary skill in the art could, without undue experimentation, design primers with the required characteristics.

As noted in Applicants' Amendment dated April 18, 2003, "[s]uch primers could be easily be identified given the sequence comparisons of Figures 8-11, 17 and 21."

Claims 30 and 31

With respect to Claim 30, and Claim 31 which depends therefrom, Figure 17C, seventh line, shows a sequence as noted above (bolded section in quote from specification) for the differential diagnosis of European (Lelystad) virus from North American (Iowa) strains, wherein there are a number of nucleotides deleted in Lelystad which are present in all of VR 2385 (ISU-12), ISU-1894 (VR 2475), ISU-22 (VR , ISU-79 (VR 2474), ISU-55 (VR 2430) and ISU-3927 (VR 2431), which are the specific strains recited in both Claim 30. Using this sequence (e.g., "---...C..---GCC") as one of the required primers, one of ordinary skill in the art could amplify the Iowa strains without amplifying Lelystad.

Claims 39 and 40

Specific support for pairs of primers which can identify both the Iowa strain and the Lelystad strain (Claims 39 and 40) can be found at pp. 88-89 of the specification. These primer pairs (SEQ ID NOS 8 and 9, 9 and 10, and 11 and 12) were based on the Lelystad sequence, but were effective at identifying Iowa strain

VR 2385 (see p. 89, ll. 1-5 of the specification). Thus, in the case of Claim 39, not only is there a teaching in the specification and Figures of how one would design such primers, there is also an Example, containing three exemplary primer pairs (SEQ ID NOS 8 and 9, 9 and 10, and 11 and 12) based on Lelystad sequences, which were also able to positively identify Iowa strain VR 2385.

That the written description in the present specification is adequate is supported by Example 9 of the SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES used by the U.S. Patent and Trademark Office. Like the sequence in Example 9, the primers of Claim 39 are nucleotide sequences which hybridize under specific conditions (i.e., at a temperature of from 25 to 75 degrees C) to identified sequences. In the present case, the identified sequences are those of the Iowa strain and Lelystad viruses, included in Figures 8-11, 17 and 21.

Example 9 of the Written Description Guidelines notes that the claim is drawn to a genus of nucleic acids all of which must hybridize with the known sequence under specific conditions. While Example 9 requires that the sequence encodes a protein with a specific activity, the present Claims (e.g., Claims 30 and 39) require that the primer sequences have a particular function, namely, that they selectively amplify a North American strain selected from the group of specific Iowa strains, and do not amplify the European strain, Lelystad (Claim 30) or that the primers amplify both the Iowa strains and Lelystad (Claim 39). Like in Example 9, there are specific species disclosed (pp. 88-89 of the specification). By analogy, a representative number of species is disclosed in the present specification, since specific hybridization conditions in combination with the specific amplification function of the DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention. As such, withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. §112, second paragraph

Claim 41 stands rejected under 35 U.S.C. §112, second paragraph, because the Examiner alleges that Applicants discussed additional pairs of primers, SEQ ID NOS:1 and 2 and 3 and 4 in the Remarks section of their previous Amendment, but

only includes primer pairs SEQ ID NOS: 8 and 9, SEQ ID NOS: 9 and 10, and SEQ ID NOS: 11 and 12 in Claim 41. This rejection is respectfully traversed.

In the Office Action dated March 4, 2004, the Examiner points to the "Remarks" portion of Applicants' Amendment, wherein Applicants mistakenly stated the following:

> New Claim 41 has also been added, which is dependent on Claim 39, which is directed to a diagnostic kit for assaying PRRSV, wherein the primers amplify not only the Iowa strains, but also the Lelystad strain. The recited pairs of primers, SEQ ID NOS 1 and 2, 3 and 4, 8 and 9, 9 and 10 and 11 and 12, are based on the Lelystad sequence (see, e.g., Figures 8, 9 and 11 as highlighted and attached), yet they still identify VR 2385, an Iowa strain.

However, this latter sentence clearly contained a typographical error, because Claim 41, as added in that Amendment, plainly only referred to primer pairs SEQ ID NOS:8 and 9, 9 and 10 and 11 and 12. Furthermore, on page 10 of that Amendment, Applicants noted the following:

> As to Claim 39, specific support for pairs of primers which can identify both the Iowa strain and the Lelystad strain can be found at pp. 88-89 of the specification. These primer pairs (SEQ ID NOS 8 and 9, 9 and 10, and 11 and 12) were based on the Lelystad sequence, but were effective at identifying Iowa strain VR 2385 (see p. 89, ll. 1-5 of the specification).

Applicants submit that the misstatement at p. 9 of Applicants' amendment regarding which pairs of primers were recited by Claim 41 should not be construed as suggesting that Applicants did not consider primer pairs SEQ ID NOS 8 and 9, 9 and 10, and 11 and 12 to be "their invention". While other primer pairs are certainly recited in the specification, Applicants chose in Claim 41 to only specifically claim certain primer pairs.

In light of the foregoing, withdrawal of this rejection is respectfully requested.

IX. Conclusion

In light of the foregoing, Claims 30, 31 and 39-41 are patentable, and a finding of such is respectfully requested.

Respectfully submitted,

Burns, Doane, Swecker & Mathis, L.L.P.

Date September 7, 2004 By: Sharon E. Crane

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APPENDIX A

The Appealed Claims

30. (Previously presented) A diagnostic kit for the differential diagnosis of North American and European porcine reproductive and respiratory syndrome virus (PRRSV), comprising:

(a) a first primer comprising a polynucleotide having a sequence of from 10 to 50 nucleotides in length which selectively hybridizes to a genomic polynucleic acid from a North American strain of PRRSV, wherein said North American strain is an Iowa strain of PRRSV selected from the group consisting of ISU-22 (VR 2385 or VR 2386), ISU-22 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), ISU-79 (VR 2474) and ISU-1894 (VR 2475), at a temperature of from 25 to 75°C,

(b) a second primer comprising a polynucleotide having a sequence of from 10 to 50 nucleotides in length which selectively hybridizes to said genomic polynucleic acid from said Iowa strain of PRRSV at a temperature of from 25 to 75°C and being downstream from the sequence to which said first primer hybridizes, and

(c) a reagent which enables detection of an amplified polynucleic acid, wherein said primers selectively amplify said North American strain and not a European PRRSV strain, wherein said European strain is Lelystad.

31. (Original) The diagnostic kit of Claim 30, wherein said reagent is an intercalating dye, the fluorescent properties of which change upon intercalation into double-stranded DNA.

39. (Previously presented) A diagnostic kit for assaying a porcine reproductive and respiratory syndrome virus, comprising:

(a) a first primer comprising a polynucleotide having a sequence of from 10 to 50 nucleotides in length which hybridizes to a genomic polynucleic acid from an Iowa strain of porcine reproductive and respiratory syndrome virus selected from the group consisting of ISU-22 (VR 2385 or VR 2386), ISU-22 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), ISU-79 (VR 2474) and ISU-1894 (VR 2475), and also hybridizes to polynucleic acid from Lelystad virus at a temperature of from 25 to 75°C,

(b) a second primer comprising a polynucleotide having a sequence of from 10 to 50 nucleotides in length which hybridizes to said genomic polynucleic acid from said Iowa strain of porcine reproductive and respiratory syndrome virus, and also hybridizes to polynucleic acid from Lelystad virus at a temperature of from 25 to 75°C and being downstream from the sequence to which said first primer hybridizes, and

(c) a reagent which enables detection of an amplified polynucleic acid.

40. (Previously presented) The diagnostic kit of Claim 39, wherein said reagent is an intercalating dye, the fluorescent properties of which change upon intercalation into double-stranded DNA.

41. (Previously Added) The diagnostic kit of Claim 39, wherein said primers are selected from the group consisting of SEQ ID NOS:8 and 9, SEQ ID NOS:9 and 10, and SEQ ID NOS:11 and 12.